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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/226,044 01/05/99 HOFFMAN

A UWS-102

EXAMINER

HM12/0327

KISHORE, G

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

03/27/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/226,044

Applicant(s)

Hoffman

Examiner

Gollamudi Kishore, Ph.D

Group Art Unit

1615



☒ Responsive to communication(s) filed on Jan 5, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, ^{Substantive} PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, ^{Substantive} PTO-948

☐ Notice of Informal Patent Application, PTO-152

GSK
Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

What is being claimed in claim 1? The claim is drawn to a composition and also recites a 'means'. According to the dependent claims 3 and 4, the means is light or ultrasound, radiation, or an electric field. How can one have a composition containing 'ultrasound' or 'light'? Does the composition have a radioactive material in the composition to emit radiation? The distinction between 'cell membranes' and 'cell barriers' in claim 1 is unclear. Membranes are barriers and vice versa.

'the means for inducing the membrane barrier transport enhancing agent' in claim 3 has no antecedent basis. Furthermore, claim 3 depends from itself.

What is being conveyed by 'monomeric units prepared from monomers' and 'polymers including one or more polymeric blocks comprising proteins or peptides which include imidazole groups' in claim 7? The use of the terms comprising, including and

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include in the same expression is confusing. Proper Markush terminology should be followed in this claim.

Where are the lysosome degrade and what is the compound which decreases the degradation as recited in claim 9?

What is the distinction between the polymer in claim 1 and polymer in claim 11?

The distinction between 'nucleic acid' and 'nucleic acid molecule in claim 12 and , liposomes and lipid vesicles in claim 13 is unclear.

How can the administration of a composition into a cell result in the transport of the molecules out of the cell as recited in claim 19? What are these molecules?

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-3, 5-6, 8-10, 13, 15, and 17-19 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/33520.

WO discloses pH sensitive liposomes containing polylysine and a therapeutic agent (note the abstract and claims). The reference meets the requirements of instant claims.

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This rejection will be withdrawn once a determination of the subject matter in the provisional application is determined. Applicant is requested to clarify the issue.

5. Claims 1-3, 5-7, 9, 15, 18 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Herbig (5,609,590).

Herbig discloses beads containing pH sensitive polymers and therapeutic agents (note the abstract, examples and claims).

6. Claims 1-16, and 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 97/04832 or WO 97/09068 both are of record.

WO 04832 discloses transdermal delivery of various drugs including nucleic acids using ultrasound. The drugs are encapsulated in either liposomes or polymer particles. The compositions further include phospholipid disrupting agents (note the abstract, pages 11-25, examples and claims).

WO 09068 teaches stimuli-responsive polymer systems for drug delivery (note the entire patent).

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1-7, 9-10, 14-16, and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Shapland (5,807,306).

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Shapland discloses drug delivery using ultrasound or iontophoresis (note the abstract, column 16 and claims).

8. Claims 1-3, 5-6, 8-13, 15, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Lishko (5,753,263).

Lishko teaches pH sensitive liposomal compositions containing a polymer or a synthetic peptide for the delivery of nucleic acids (note column 15, line 13 et seq., and col. 20).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-7, 9, 15, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Chien (5,362,308).

Chien discloses iontophoretic delivery of drugs and the composition contains a polymer (note the abstract, examples and claims).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1602